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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,421	04/09/2004	Peter Ospyka	32469-303686	1219

7590 05/25/2006

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EXAMINER

BERTRAM, ERIC D

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/821,421

Applicant(s)

OSPYKA, PETER

Examiner

Eric D. Bertram

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 18-65 is/are pending in the application.
- 4a) Of the above claim(s) 23,26-30 and 51-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 18-22,24,25,31-40 and 42-50 is/are rejected.
- 7) ☒ Claim(s) 41 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/5/04, 10/22/04</u>  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Claims 18-22, 24, 25 and 31-50 in the reply filed on 5/8/2006 is acknowledged.
2. Claims 23, 26-30 and 51-65 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/8/2006.

### ***Priority***

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Information Disclosure Statement***

4. The information disclosure statements (IDS) submitted on 8/5/2004 and 10/22/2004 were filed in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

### ***Drawings***

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the loop structure at a connection point near an exit opening must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended

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replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 37 recites the limitation "the stop" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.
8. Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 41 recites the limitation "the exit openings" in line 2 of

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the claim. There is insufficient antecedent basis for this limitation in the claim. Only one "exit opening" had been defined prior to this limitation.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 18-22, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Worley et al. (Applicant cited NPL, hereinafter Worley). Worley discloses an apparatus for inserting an electrode into the myocardium of the heart, the apparatus including an anchor for abutting a surface of the heart, the anchor having an attachment area with a region of reduced cross sectional area at the trailing end for receiving a thin stylet tool that helps to insert the anchor through the myocardium to an operating position (see figures 3 and 4). Further attached to the anchor is a tension element, which in this case is 4-0 Nylon monofilament (see text on page H531). Worley further discloses a receiver tube in the form of Teflon tubing, which defines a lumen adapted to hold the anchor and the tool while the tubing pre-forms a canal through the myocardium, as shown in figure 3A. The anchor also has a position for deployment in

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the myocardium, as shown in figure 3A, and also has an expanded position at the operating position as shown in figure 3B.

11. Regarding claim 31, although Worley does not specifically state that the stylet is flexible, based on the fact that the stylet is made from 25-gauge wire, the stylet would inherently have some flexibility due to its small diameter.

12. Claims 18, 32, 33, 35, 36, 38, 43, 44, 46-48 and 50 are rejected under 35 U.S.C. 102(e) as being anticipated by Shchervinsky (US 6,941,174). Shchervinsky discloses an apparatus with an anchor 20 for abutting a surface of the heart, a tension element 26 attached to the anchor and a tool 16 which is detachably coupled to an attachment area of the anchor and helps insert the anchor through the myocardium to an operating position (see figures 1 and 8 and Col. 4, lines 1-6). Shchervinsky further shows that the apparatus has anode and cathode electrodes 22, 24 for stimulating the myocardium, and the electrodes each have an inner, circular lumen (i.e. a loop) that allows the tension element 26 to pass through and connect to the electrodes near the exit openings of the lumen (figure 1 and Col. 4, lines 7-16).

13. Regarding claims 36 and 47, Shchervinsky shows in figure 1 that electrode 22 is attached to the tension element and protrudes out from the tension element. It is the Examiner's position that the electrode will inherently act as a stop which acts to prevent movement in either a forward or rearward direction due to its protruding structure.

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Worley in view of Makower et al. (US 6,491,707, hereinafter Makower). Worley, as

described above, discloses the applicant's basic invention, including an opening for

receiving an insertion tool. Worley does not disclose, however, that the anchor is rod

shaped, with the tension element attached to the anchor between the first and second

end. Attention is directed to the secondary reference of Makower, which discloses a

rod-shaped anchor 30a with a tension element 30c attached between the first and

second ends in order to securely attach the anchor to bodily tissue (see figure 12).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the

applicant's invention to modify the anchor of Worley by making it rod-shaped as taught

by Makower since this is a design for tissue anchors that is old in the art.

17. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over

Shchervinsky in view of Official Notice. Shchervinsky discloses the applicant's basic

invention, including having the electrode define a lumen with an exit point for the tension

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element, wherein the tension element and the electrode are mechanically attached, effectively sealing the exit point (Col. 4, lines 26-34). Shchervinsky does not disclose, however, that the mechanical attachment is formed through the use of medical adhesive. However, the Examiner takes Official Notice that the use of medical adhesive in implantable devices for mechanical attachment is notoriously old and well known in the art and it would have been obvious to one of ordinary skill in the art to use medical adhesive since it provides strong mechanical attachment while being safe to use in the body.

18. Claims 39, 40 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Worley in view of Wesbey et al. (US 3,244,174, hereinafter Wesbey). Worley, as described above, discloses the applicant's basic invention with the exception of having two electrodes branching from a common supply lead for stimulating the heart.

Attention is directed to the secondary reference of Wesbey, which discloses a system for implanting multiple conductors in a heart by inserting two conductors 24 extending from a common supply lead into the myocardium of the heart, as shown in figure 1.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the system of Worley by adding two electrodes extending from a common supply as taught by Wesbey in order to stimulate two locations of the heart at the same time.

19. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shchervinsky in view of Worley. Shchervinsky, as described above, discloses the applicant's basic invention with the exception of a receiver tube that holds the anchor



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and tool during insertion into the heart. Attention is directed to the secondary reference of Worley, which discloses a Teflon tubing that holds an anchor and stylet during insertion in the heart. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the system of Shchervinsky by adding the tube of Worley in order to protect the tool and anchor during insertion.

***Allowable Subject Matter***

20. Claim 41 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

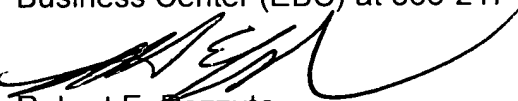
21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Robicsek (US 4,444,207) discloses an anchor and electrode system for insertion in the myocardium of the heart.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday and every other Friday from 9-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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